24 October 2018

Scancell Holdings Plc

Scancell and Ichor provide update on SCIB1 Phase 2 clinical study in patients with advanced melanoma

Scancell Holdings plc ("Scancell"), the developer of novel immunotherapies for the treatment of cancer, and Ichor Medical Systems, Inc. ("Ichor"), today provide an update on the proposed international Phase 2 clinical study of Scancell's lead ImmunoBody®, SCIB1, in combination with Keytruda (pembrolizumab), in patients with advanced melanoma.

Following the submission of an Investigational New Drug (IND) application for the clinical study to the US Food and Drug Administration (FDA), the FDA has responded requesting additional information, in particular with respect to Ichor's new TriGrid® 2.0 electroporation delivery system and its use in combination with SCIB1.

Ichor's TriGrid® 2.0 is an electroporation delivery system which is designed to support eventual commercial deployment and will be used to deliver the SCIB1 vaccine to patients in the proposed Phase 2 study. Scancell has previously used Ichor's TriGrid® 1.0 delivery system in the SCIB1 Phase 1/2 clinical study in patients with Stage III/IV malignant melanoma. In this study SCIB1 was shown to have a favorable safety profile with no dose-limiting toxicities and no serious adverse events related to study drug or the delivery device.

Scancell and Ichor are working with the FDA to provide the necessary information to enable initiation of the trial. In parallel, Scancell is continuing to work on the operational activities required to initiate clinical sites in the US and UK. Scancell anticipates that patient enrolment into this trial will commence in the first half of 2019, subject to the necessary regulatory approvals.

Cliff Holloway, CEO of Scancell, said:

"We are working closely with Ichor and the FDA to address the questions they have raised and we are confident we can respond to these in timely manner. We continue to advance the operational processes and procedures to ensure a rapid start to the study once approval is obtained."

Robert Bernard, President & CEO of Ichor, added:

"We have taken on board the comments from the FDA and are confident we can promptly respond to the questions on our TriGrid® 2.0 electroporation device. Working closely with Scancell, we aim to be trial ready in H1 2019."

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014 (MAR).

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About Scancell

Scancell is developing novel immunotherapies for the treatment of cancer based on its ImmunoBody® and Moditope® technology platforms.

ImmunoBody® vaccines target dendritic cells and stimulate both parts of the cellular immune system. They can be used as monotherapy or in combination with checkpoint inhibitors. This platform has the potential to enhance tumour destruction, prevent disease recurrence and extend survival.

- SCIB1, the lead programme, is being developed for the treatment of melanoma. A phase 1/2 clinical trial has so far successfully demonstrated survival data of more than five years.
- SCIB2 is being developed for the treatment of non-small cell lung cancer and other solid tumours. Scancell has entered into a clinical development partnership with Cancer Research UK for SCIB2.

Moditope® represents a completely new class of potent and selective immunotherapy agents. It stimulates the production of killer CD4+ T cells which overcome the immune suppression induced by tumours. allowing activated T cells to seek out and kill tumour cells that would otherwise be hidden from the immune system. Moditope® alone, or in combination with other agents, has the potential to treat a wide variety of cancers.

- Modi-1 is being developed for the treatment of triple negative breast cancer, ovarian cancer and sarcomas.

For further details, please see our website: www.scancell.co.uk

About Ichor Medical Systems, Inc.

Ichor Medical Systems' investigational TriGrid® Delivery System (TriGrid) is the first integrated and fully automated device for electroporation-mediated nucleic acid administration in humans. Ichor, a privately-held biotech company based in San Diego, CA, is collaborating with partners to provide its enabling TriGrid platform as a means for delivery of nucleic acid-based drugs and vaccines in disease indications such as cancer, hepatitis B virus (HBV) infection, human papillomavirus (HPV) infection, and human immunodeficiency virus (HIV) infection, as well as for multiple biodefense agents. The TriGrid platform is also being developed for nucleic acid-based antibody delivery as a rapid countermeasure in the event of an infectious disease outbreak or biological weapons attack. Visit http://www.ichorms.com.